

CLAIMS

What is claimed is:

5 1. A method of treating with oxybutynin a human subject having overactive bladder, while minimizing an anticholinergic or antimuscarinic adverse drug experience associated with said oxybutynin treatment therapy comprising the step of: administering as a transdermal patch, a composition comprising oxybutynin to said subject to provide a plasma area under the curve (AUC) ratio of oxybutynin to an oxybutynin metabolite of from about 0.5:1 to about 5:1 with a peak oxybutynin metabolite plasma concentration of less than about 8 ng/ml, wherein the transdermal patch optionally includes a permeation enhancer.

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15 2. The method of claim 1, wherein the AUC ratio of oxybutynin to an oxybutynin metabolite is from about 1:1 to about 5:1.

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3. The method of claim 2, wherein the AUC ratio of oxybutynin to an oxybutynin metabolite is from about 0.8:1 to about 1.5:1.

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4. The method of claim 1, wherein the metabolite of oxybutynin is N-desethyloxybutynin.

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5. The method of claim 4, wherein the N-desethyloxybutynin is (R)-N-desethyloxybutynin, (S)-N-desethyloxybutynin or a combination thereof.

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6. The method of claim 1, wherein the oxybutynin is a mixture of R-oxybutynin and S-oxybutynin.

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7. The method of claim 6, wherein the oxybutynin is R-oxybutynin.

8. The method of claim 1, wherein the peak metabolite plasma concentration is less than about 5 ng/ml.

9. The method of claim 1, wherein the oxybutynin metabolite is N-desethyloxybutynin and the N-desethyloxybutynin plasma concentrations are below about 2.0 ng/ml at about 6 hours after administration.

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10. The method of claim 1, wherein the oxybutynin metabolite is N-desethyloxybutynin and oxybutynin and N-desethyloxybutynin plasma concentrations are below about 8 ng/ml at about 24 hours after initial administration.

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11. The method of 10, wherein the oxybutynin wherein the metabolite is N-desethyloxybutynin and at steady state, the oxybutynin and N-desethyloxybutynin plasma concentrations are below about 8 ng/ml for the duration of administration.

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12. The method of any of claims 1-11 wherein the transdermal patch is administered for a duration of from about 24 to about 96 hours.

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13. The method of claim 12, wherein the duration of administration is between 72 and 96 hours.

14. The method of claim 13, wherein the duration of administration is 72 hours.

15. The method of claim 13, wherein the duration of administration is 84 hours.

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16. The method of any of claims 1-11, wherein the transdermal patch has a size of from 13 cm² to 39 cm².

17. The method of claim 16, wherein the patch size is 13 cm².

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18. The method of claim 16, wherein the patch size is 39 cm².

19. The method of claim 16, further comprising the step of concurrently

administering multiple patches to the subject.

20. The method of claim 19, wherein the plurality of patches is a plurality of 13 cm² patches.

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21. An article of manufacture for transdermal application comprising:

10 a transdermal patch including a composition of oxybutynin and optionally a permeation enhancer for administration to a human subject, wherein the patch provides upon administration, a plasma AUC ratio of oxybutynin to an oxybutynin metabolite from about 0.5:1 to about 5:1 with a peak oxybutynin metabolite concentration of about 8 ng/ml, and wherein said patch minimizes an anticholinergic or antimuscarinic adverse drug experience associated with the administration of oxybutynin.

15 22. The article of manufacture of claim 21, wherein the AUC ratio of oxybutynin to an oxybutynin metabolite is from about 1:1 to about 5:1.

23. The article of manufacture of claim 22, wherein the AUC ratio of oxybutynin to an oxybutynin metabolite is from about 0.8:1 to about 1.5:1.

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24. The article of manufacture of claims 21, wherein the metabolite of oxybutynin is N-desethyloxybutynin.

25 25. The article of manufacture of claim 24, wherein the N-desethyloxybutynin is (R)-N-desethyloxybutynin, (S)-N-desethyloxybutynin or a combination thereof.

26. The article of manufacture of claim 21, wherein the oxybutynin is a mixture of R-oxybutynin and S-oxybutynin.

30 27. The article of manufacture of claim 26, wherein the oxybutynin is R-oxybutynin.

28. The article of manufacture of claim 21, wherein the peak oxybutynin

metabolite concentration is about 5 ng/ml.

29. The article of manufacture of claim 21, wherein the oxybutynin metabolite is N-desethyloxybutynin and the N-desethyloxybutynin plasma concentrations are 5 below about 2.0 ng/ml at about 6 hours after administration.

30. The article of manufacture of claim 21, wherein the oxybutynin metabolite is N-desethyloxybutynin and oxybutynin and N-desethyloxybutynin plasma concentrations are below about 8 ng/ml at about 24 hours after initial administration.

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31. The article of manufacture of 30, wherein the oxybutynin wherein the metabolite is N-desethyloxybutynin and at steady state, the oxybutynin and N-desethyloxybutynin plasma concentrations are below about 8 ng/ml for the duration of 15 administration.

32. The article of manufacture of any of claims 21-31 wherein the transdermal patch is administered for a duration of from about 24 to about 96 hours.

20 33. The article of manufacture of claim 32, wherein the duration of administration is between 72 and 96 hours.

34. The article of manufacture of claim 33, wherein the duration of administration is 72 hours.

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35. The article of manufacture of claim 13, wherein the duration of administration is 84 hours.

30 36. The article of manufacture of any of claims 1-11, wherein the transdermal patch has a size of from 13 cm² to 39 cm².

37. The article of manufacture of claim 36, wherein the patch size is 13 cm².

38. The article of manufacture of claim 36, wherein the patch size is 39 cm².
39. The article of manufacture of claim 36, further comprising the step of concurrently administering multiple patches to the subject.
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40. The article of manufacture of claim 39, wherein the plurality of patches is a plurality of 13 cm² patches.
- 10 41. A method of treating with oxybutynin a human subject having overactive bladder, while minimizing an anticholinergic or antimuscarinic adverse drug experience associated with said oxybutynin treatment therapy comprising the step of: administering as a transdermal patch having a size of from 13 cm² to 39 cm² a composition comprising oxybutynin to said subject for a duration of from about 24 to 15 about 96 hours to provide a plasma area under the curve (AUC) ratio of oxybutynin to an oxybutynin metabolite of from about 0.5:1 to about 5:1 with a peak oxybutynin metabolite plasma concentration of less than about 8 ng/ml, wherein the transdermal patch includes an effective amount of a permeation enhancer selected from the group consisting essentially of: fatty acids, fatty acid esters, fatty alcohols, fatty acid esters 20 of lactic acid or glycolic acid, glycerol di- and monoesters, short chain alcohols, and mixtures thereof.